# Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

Supplement to: Takuva S, Takalani A, Garrett N, et al. Thromboembolic events in the South African Ad26.COV2.S vaccine study. N Engl J Med. DOI: 10.1056/NEJMc2107920

# Supplementary Appendix

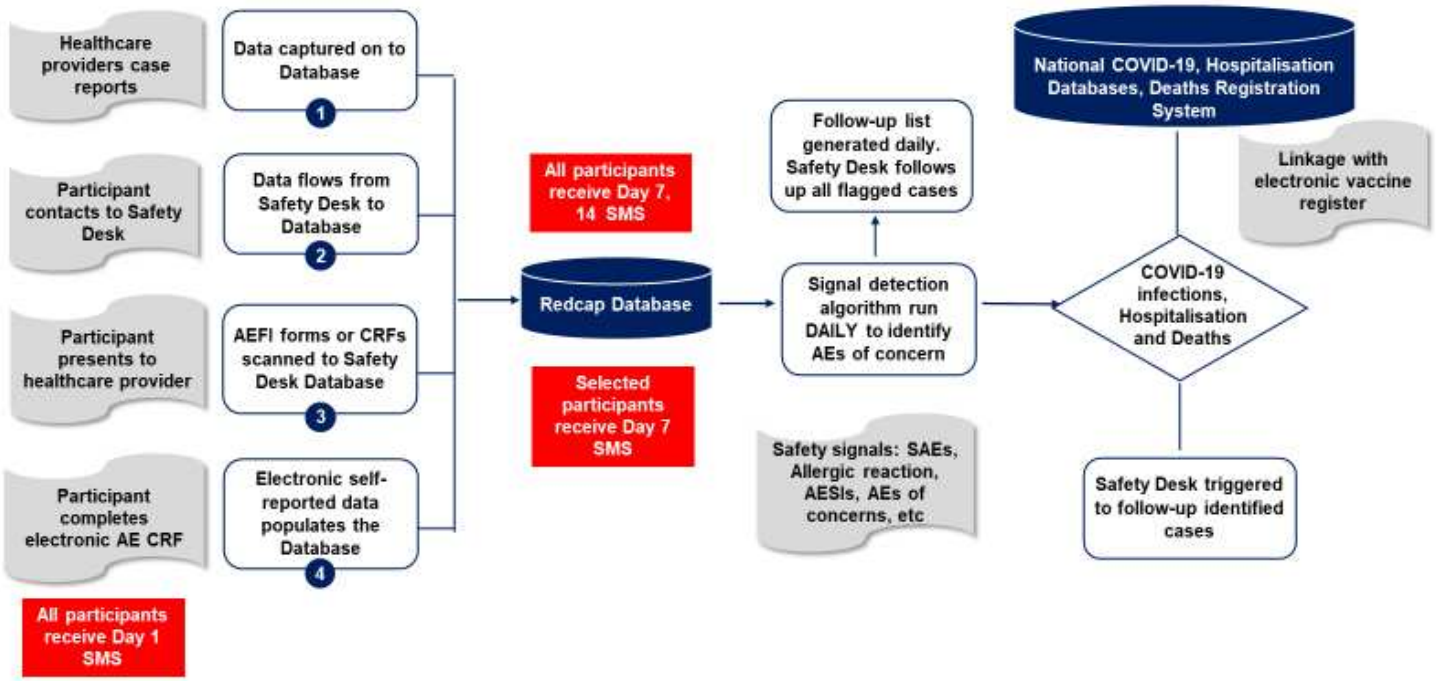
## Table of Contents

**Table 1:** Distribution of Serious Adverse Events and Adverse Events of Special Interest in the Sisonke study by System Organ Class

| System Organ class | Total | % of all persons vaccinated | Study Rate per 100,000 vaccinated |
|---|---|---|---|
| **Infections and infestations** | **15** | 0.005% | 5.2 |
| COVID-19 disease | 12 | 0.004% | 4.2 |
| Bronchopneumonia or TB | 3 | 0.001% | 1.0 |
| **Immune system disorders** | **15** | 0.005% | 5.2 |
| Allergic conditions (excluding anaphylaxis) | 11 | 0.004% | 3.8 |
| Anaphylaxis | 1 | <0.001% | 0.3 |
| Autoimmune disorders | 3 | 0.001% | 1.0 |
| **Vascular disorders** | **6** | 0.002% | 2.1 |
| Pulmonary embolism | 2 | 0.001% | 0.7 |
| Cerebrovascular accident | 2 | 0.001% | 0.7 |
| Retinal vein occlusion and macular haemorrhage | 1 | <0.001% | 0.3 |
| Intracranial hypertension | 1 | <0.001% | 0.3 |
| **Nervous system disorders** | **5** | 0.002% | 1.7 |
| Guillain-Barré Syndrome | 1 | <0.001% | 0.3 |
| Bell's palsy | 1 | <0.001% | 0.3 |
| Neuralgia | 1 | <0.001% | 0.3 |
| Seizure | 1 | <0.001% | 0.3 |
| Severe migraine | 1 | <0.001% | 0.3 |
| **Metabolism and nutritional disorders** | **2** | 0.001% | 0.7 |
| Glucose metabolism disorders | 2 | 0.001% | 0.7 |
| **Musculoskeletal and connective tissue disorders** | **3** | 0.001% | 1.0 |
| **Hepatobiliary disorders** | **1** | <0.001% | 0.3 |
| **Infections and infestations with Gastrointestinal disorders** | **1** | <0.001% | 0.3 |
| **Injury, poisoning and procedural complications** | **1** | <0.001% | 0.3 |
| **Renal and urinary disorders** | **1** | <0.001% | 0.3 |
| **Total** * | **50** | 0.017% | 17.3 |

*In total, there have been seven deaths in the study. Four participants aged 55, 56, 58 and 62 died of COVID-19 disease within 21 days of vaccination. One participant already mentioned above died of a pulmonary embolism, one of gastrointestinal bleeding from oesophageal varices and portal hypertension, and one from advanced HIV-Tuberculosis co-infection, renal failure and Escherichia coli septicaemia.

**Figure 1** Overview of the Sisonke Phase 3B Study Pharmacovigilance System




Sisonke safety assessment is through a combination of passive reporting and active case finding of reactogenicity and adverse events. In addition, a pharmacovigilance system is in place to identify COVID-19 breakthrough infections, hospitalisations and deaths through existing national databases that are linked into the study via the national identity number. Following vaccination, HCWs receive advice on side-effects and an electronic adverse event reporting link via text message on Day 1 and Day 7. Furthermore, adverse events can be reported either by calling a toll-free 24-hour safety desk or by completing an adverse event report form that is available at all vaccination sites and hospitals.